

outcomes, the main fields covered by PROs (such as quality of life) in chronic diseases will be described. We will develop PRO measurement issues, notably psychometric properties and cultural adaptations, and also differences between generic and disease-specific instruments, with quality of life instruments as an example. Then we will define the use of PROs data in the field of adherence research, with their advantages and limitations compared with other sources of data. Last, the actual or potential impact of PROs will also be examined in terms of quality of care for daily medical practice and research issues.

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## CLINICAL PHARMACOLOGY IN HEALTH CARE IN CROATIA

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**Summary:** The new manifesto on clinical pharmacology (CP) emphasizes the importance of CP in delivery of health care, the role of CP that has not always been played the way and in the extent it was hoped for. In Croatia, CP has been recognized as a separate medical discipline/specialty since 1974. Since then, >30 physicians have been trained in CP and work in various health care settings across country. Depending on the setting, they provide CP services, conduct research, and are involved in teaching. In some settings, clinical pharmacologists provide direct patient care, having a direct responsibility for patients, but more commonly provide a range of services to clinical colleagues and their patients as well as serve as consultants in regulatory and administrative bodies dealing with medications. Although specialists in CP, not all clinical pharmacologists involved in health care belong to established departments/units of CP. Differences in organizational models for delivering CP services to health care probably arise from not adequately defined functions of CP. The functions have been well defined in the new Manifesto but not well recognized by relevant bodies. We should not be ignoring the challenging future of CP in health care.

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## THE SCOTTISH MODEL: SCOTTISH MEDICINES CONSORTIUM (SMC)

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**Summary:** UK health care is provided by a national health service (NHS), within which medicines are a major and growing cost. Concerns from patients, politicians, medical practitioners, and the press about “postcode” prescribing (marked regional differences in availability of newly licensed medicines) led to the creation of the Scottish Medicines Consortium (SMC). Run by NHS clinicians, SMC provides rapid advice on all new medicines, including new indications/formulations for existing therapies. A streamlined 2-stage pharmacy and health economic, and then strategic, review of submissions from industry by SMC provides an objective review of the data and a wider societal view of need. A patient perspective is included. Comparative cost-effectiveness is assessed, preferably by using QALY ICERs, and advice given close to UK licensing (usually within 4 months). This early advice means that physicians are prepared to wait for the decision from SMC, and prescribing is relatively uncommon outside the guidance. Three outcomes are possible: (1) accept for general use; (2) accept with restriction (by specialist prescriber, or only for a subgroup within the license); or

(3) do not recommend for use in Scotland. Appeals can be heard and resubmissions can be made if the evidence base changes. Around 1000 submissions have now been made, including abbreviated submissions for minor license changes, since 2002. Around two thirds of all medicines were accepted for use in NHS Scotland but many in a way more restrictive than the license. Around 50% of resubmissions are accepted. Evidence suggests SMC decisions are not influenced by budget impact (affordability) but are strongly influenced by whether the drug provides value for money to the NHS in Scotland. Accepted modifiers of decisions include orphan indications, end-of-life treatment, bridging to a definitive treatment, and the development of licensed treatment where only an unlicensed preparation previously existed. Drug utilization data suggest that early advice influences prescribing patterns, in a positive way for approved drugs, and by lack of uptake (or reduction of existing prescribing) for those not recommended (with some exceptions). Benchmarking shows a high level of consistency with subsequent decisions from the National Institute for Health and Clinical Excellence (NICE), and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia. SMC has an ongoing horizon scanning program, created a Scottish Management of Antimicrobial Resistance action Plan (ScotMARAP; 2008), and now runs a Patient Access Scheme to make high-cost drugs affordable to Scottish patients. An open and inclusive process, involving key stakeholders, can produce useful, rigorous, evidence-based advice to a health care system in a way that is acceptable to the NHS and to the pharmaceutical industry, and occurs sufficiently early after the launch of a new drug to inform and influence subsequent prescribing patterns.

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## NEW MEDICINES FOR CONTROL AND ELIMINATION OF MALARIA

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**Summary:** Despite being 1 of the most prevalent tropical diseases, for many years malaria was not a commercial priority for the pharmaceutical industry. However, in response to the emergence and spread of resistance to the available antimalarial drugs, there has been a renaissance in the discovery and development of new medicines to control the disease in the last few years. The persistent threat of resistance means that new molecules with novel mechanisms of action are continually required. Furthermore, the recent call for the elimination and eradication of malaria has prompted an extension of the stages of the life cycle of malaria parasites that should be targeted by new molecules. Recent advances in genome-based technologies and in vitro screening of whole parasites have broadened the range of therapeutic targets and are accelerating the development of a new generation of treatments for both malaria control and eradication.

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## NETWORKING FOR REGULATORY TOXICOLOGY

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**Summary:** The purpose of regulatory toxicology is to evaluate all available information relevant to the toxicity of agents, which may be biological, chemical, or physical in nature, on behalf of governmental or international organizations. The aim is to protect workers, consumers, the public generally, and the environment. Wherever possible, this is done through a process of quantitative or qualitative risk